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In the Supreme Court of the United States

OCTOBER TERM, 1979

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

RAY MARSHALL, SECRETARY OF LABOR, PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

REPLY BRIEF FOR THE FEDERAL PARTIES

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1. The court of appeals held that the Secretary may promulgate an OSHA standard under 29 U.S.C. 655(b) only where he demonstrates that the standard

will produce "measurable" or "quantifiable" health benefits (*i.e.*, lives saved), and, after quantifying the health benefits, the Secretary demonstrates that they "bear a reasonable relationship" to the standard's cost. Where the Secretary is unable to demonstrate quantifiable benefits because the epidemiological data are too incomplete to permit reliable estimates, no standard at all may issue even where the Secretary draws the *qualitative* conclusion, based on experience and expert opinion, that the standard will provide an appreciable measure of occupational health protection (Pet. App. 17a-21a n.23, 24a).

Although respondents support the holding below, they also urge affirmance on the narrower theory that no OSHA standard may be issued where the Secretary does not "consider" "educated estimates" of health benefits from reduced exposure, at least where, as respondents contend is true here, such estimates are possible (API Br. 21-24, 27, 29, 33, 43, 69-70, 73-75) and the standard will require an expenditure of "enormous resources to prevent a *de minimis* health risk" (*id.* at 25, 29, 31-35, 36-41, 81 n.121). The factual premises from which this argument proceeds, however, are foreclosed by the Secretary's findings based on substantial evidence.

a. The Secretary "considered" extensive evidence on both sides of the question of whether sufficiently accurate exposure data existed to permit a reliable risk assessment for long-term, low-level

exposure to benzene, and he explained why, in his judgment, such extrapolations are not possible for benzene based on existing data (see Pet. App. 96a, 112a-115a, 117a, 125a, 132a, 160a, 182a-185a; and our opening brief at pages 63-69)[1] The Secretary's finding, resting as it does on substantial evidence, is "conclusive," 29 U.S.C. 655(f), and forecloses respondents' contrary assertion.

Respondents seek to discredit the Secretary's conclusions with the argument that a physicist who testified for respondents (Dr. Wilson) was able to prepare an "upper-bound" risk assessment for benzene. This risk assessment, respondents claim (API Br. 20-21), demonstrates that, at most, only two cancers would be saved every six years by the benzene standard. Respondents claim that Dr. Wilson avoided the pitfalls of the unknown by employing "conservative" assumptions for every unknown factor or relationship and thus obtained an "upper bound" estimate of the maximum possible health benefits (that is, the health

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[1] See Tr. 30, 152, 287-288, 352, 359, 363-364, 401-402, 414, 417, 746, 761, 777, 895, 925, 1053, 1067, 1178-1189, 1210, 1214-1215, 1227, 1229, 1327, 2500, 2520-2521; Exhs. 17 at 7, 149-D at 15, 2.B-272 at 1; see also the Secretary's preamble to the coke ovens standard on this issue (41 Fed. Reg. 46742 (1976)), incorporated by reference in the benzene preamble (Pet. App. 163a). The court of appeals agreed with the Secretary's conclusion but speculated that such risk assessments would be possible in the future (Pet. App. 18a-19a n.23, 21a, 23a). Contrary to respondents' assertions (API Br. 73-74, 76-78), the court did not hold that a risk assessment like Dr. Wilson's would have satisfied its test.

benefits could not be more, but could be less, than two lives saved every six years).

In fact, as we show in Appendix A, *infra*, Dr. Wilson did not employ "conservative" assumptions. For example, although respondents claim (API Br. 76, 80 n.119) that Dr. Wilson based his demonstration on the Infante data, he did no such thing. To the contrary, Dr. Wilson apparently decided (A. 171) that application of his predetermined mathematical model (a straight line on a graph) to the Infante data would result in too great an excess risk, and he inexplicably drew a line in his diagram (*ibid.*) at an *assumed* risk many times lower than that indicated by the Infante data.[2] In Appendix A, we have itemized these and other assumptions made by Dr. Wilson. We also show that by using different and "conservative" assumptions, the Secretary's benzene standard will save 1380 leukemias every five years—800 times the number obtained by Dr. Wilson. We do not contend that the latter estimate is any more valid than

[2] Indeed, Dr. Wilson's assumed risk line is many times lower than that indicated by the Infante data, even if the Infante data reflect average exposures at 100 ppm, as respondents claim (API Br. 12-14). In this connection, respondents are less than frank in their assertion (API Br. 80 n.119) that "[w]hat OSHA fails to disclose (if, indeed, it ever considered comparing Infante's and Wilson's results) is that Infante's findings are equivalent to slightly *less* than 2 cases every six years" and that "Dr. Wilson reached approximately the same result in applying the Infante data * * *." As stated above, Dr. Wilson did *not* extrapolate from the Infante data, and it is not clear from his testimony, statement or diagram (see A. 170-171) that he extrapolated from any data at all.

Dr. Wilson's. Our point is that the severe incompleteness of epidemiological data for benzene, combined with the uncertainty inherent in such exercises, precludes any meaningful use of even an "upper bound" risk assessment for purposes of setting an occupational health standard for benzene.[3]

[3] Respondents' contention (API Br. 22-23) that the Secretary's preamble did not give a "coherent and rational" rejection of Dr. Wilson's views and arguments is wrong. The preamble discusses throughout the large number of uncertainties that prevent useful risk quantification for the benzene standard (see Pet. App. 96a, 112a-115a, 117a, 125a, 160a-161a, 182a-185a). No more detailed response was required. See *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 291 (1974); 29 U.S.C. 655(b)(8), 655(e).

That the Secretary and other agencies have found risk assessment to be a useful administrative tool for estimating the excess risk posed by substances *other* than benzene lends no support to respondents' factual claim that the technique is equally useful in predicting the risks associated with long-term, low-level exposures to benzene. The utility of the methodology obviously depends upon the quality of the data, the number of assumptions that must be made, and the degree of precision needed in a particular case. Respondents simply refuse to accept the fact, supported by substantial evidence, that, however precise the data may be for other substances and uses, the best available data for *benzene* are too imprecise to provide useful results for predicting risk for long-term low-level occupational exposure to that substance. Respondents' reliance on a preliminary risk assessment concerning benzene prepared by a group at EPA is misplaced (A. 14-29). Appendix A illustrates why this report is inconsistent with Dr. Wilson's estimates, and why, as EPA itself concluded, its estimates could be in error by "several orders of magnitude" (A. 25). For the view that there is no such thing as a "conservative" upper bound risk assessment, due to the inability to identify truly conservative assumptions, see Cornfield, *Carcinogenic Risk Assessments*, 198 Science 693, 695-696 (1977).

b. Respondents contend (API Br. 13-17, 30, 32, 81 n.121) that "uncontradicted evidence" in the record shows that the risk of leukemia at lifelong exposures to benzene at 10 ppm is *de minimis*," "insignificant," "exceedingly small," and "miniscule." As we have already mentioned, however, the Secretary specifically found that the risk could not be quantified or usefully approximated based on currently available evidence and that, based on present knowledge, no level of exposure could be considered safe. In light of that finding, which is supported by substantial evidence, there is no merit to respondents' argument that the record affirmatively shows that the excess risk of cancer at existing levels of exposure is "*de minimis*."[4]

Respondents' contrary claim rests on misinterpretation of the "positive" studies and blind fidelity to discredited "negative" studies. To begin with, respondents' suggestion (API Br. 8) that "none" of

[4] The court of appeals expressly upheld the Secretary's determination that low levels of exposure to benzene pose a cancer risk and held only that the Secretary had not been able to adduce substantial evidence as to "the extent of" that risk (Pet. App. 18a-19a). Thus, the court concluded not that the benefits of the new benzene standard *were* insignificant, but that the Secretary had failed to submit "empirical evidence" showing that the risk of not adopting that standard *was not* insignificant (*ibid.*). Nor did the court below hold that the benefits could be estimated. To the contrary, the court stated that "valid extrapolations *will be* possible as more is known about the effects of past exposure at higher levels" and that the Secretary's conclusion that such extrapolations were now "impossible" "may be correct" (*id.* at 19a-21a & n.23) (emphasis added)).

the positive studies showed a risk below 100 ppm ignores the fact that a study based on data at a given exposure level showing an excess risk at such level cannot negate the existence of an excess risk at any lower level. In addition, respondents inaccurately assert that the levels of exposure in the Ohio plants studied by Dr. Infante averaged approximately 100 ppm and ranged as high as 1000 ppm (API Br. 12-13). Consequently, respondents conclude that Dr. Infante found an excess risk of leukemia only because the exposure levels averaged at least above 100 ppm. In fact, however, a 1946 report of the Industrial Commission of Ohio (Pet. App. 105a) shows that the exposure levels in the plants ranged "in most instances" from "0 to 10 to 15 parts per million," thus suggesting that the study indeed reflected the excess risk at low levels of exposure.[5] On the other hand, some evidence does suggest that exposure levels at the plants may have been higher (*ibid.*). The Secretary drew the factual determination that "[b]ecause of the lack of definitive exposure data, OSHA cannot derive

[5] Moreover, epidemiological evidence concerning benzene does indicate an excess health risk at low levels. For example, three Dow Chemical workers who died from leukemia had been exposed to benzene concentrations of 2 to 9 ppm. The expected number of "normal" leukemias in this population was 0.8 (Exh. 154 at 10; see Pet. App. 108a-110a). However, the total number of leukemias found in the study, albeit higher than the normal rate, was not statistically significant. (See also Tr. 753-754.) In addition, another study (Tr. 148) reported chromosomal damage at benzene exposure levels of 5 to 25 ppm has been observed (Tr. 148; Exh. 5A at 3-3). Nonmalignant blood disorders have been observed at 10 to 20 ppm (Tr. 360-361).

any conclusions linking the excess leukemia risk observed [by Dr. Infante] with any specific exposure level" (*ibid.*). Substantial evidence supported the Secretary's conclusion that the actual Ohio exposure levels studied by Infante could *not* be determined. This finding forecloses respondents' claim that the levels studied by Dr. Infante averaged 100 ppm or more.[6]

Respondents also contend (API Br. 14) that the three principal positive studies demonstrate that "when benzene exposures were reduced below 100 ppm—*but not eliminated*—the excess incidence of

[6] In this connection, respondents dispute (API Br. 11 n.19) that the additional leukemia deaths found by Dr. Sakol among the pliofilm workers studied by Dr. Infante show an even greater risk than that found by Dr. Infante. Respondents argue that Dr. Infante stated that these cases were *not* in his study and that, in any event, the study population would have to be enlarged if these cases were added. Dr. Infante testified, however, that Dr. Sakol's patients, or at least some of them, were in his cohort (Tr. 768-769, 1198-1199), but that the additional cases of leukemia were not "found" by his study, thus "underestimating" the true excess risk (see Pet. App. 103a); he did not state that these workers were not in his cohort. Dr. Sakol also suggested that they were in Dr. Infante's cohort (Tr. 308-315). Moreover, even if it were necessary to increase the study population to include these cases, the risk would still increase dramatically—*i.e.*, instead of finding 7 leukemias in a population of 748, Dr. Infante might have found 16 out of 757. And, contrary to respondents' contention, the substantial likelihood that doctors may have misrepresented a worker's cause of death on his death certificate as aplastic anemia rather than leukemia, so that the worker's family would receive workmen's compensation, would lead to underestimation of the number of leukemia cases. The incentive to make that change exists only in connection with work-related deaths, not deaths in the general population.

leukemia * * * *ceased to occur*" (emphasis in original). This is not so. It is true that in the Aksoy study (Exh. 60), no new deaths were reported after a substitute was used in place of benzene by a studied cohort of shoemakers. However, the substitutes were analyzed at the time of the study by gas chromotography, and "[t]he result showed that the substitutes contained *no* benzene" (*id.* at 3) (emphasis added). Similarly, in the Vigliani study (Exh. 2-27) no new cases of leukemia were reported among certain workers in the rotogravure industry exposed to toluene after it was substituted for benzene in 1964 (Exh. 2-50 at 217). Although some forms of toluene contain trace amounts of benzene and other forms contain none (see Pet. App. 101a), Dr. Vigliani's study provides no basis for concluding that the substituted toluene contained benzene.[7]

[7] Respondents are correct that no excess cancer risk was found among workers at the same plants studied by Dr. Infante during a study by researchers from the University of North Carolina at a later time when benzene exposure had been reduced (but not eliminated) (Exh. 187 B-13). The researchers themselves, however, pointed out numerous flaws in their study that could have accounted for the lack of statistically significant leukemias (*id.* at 35). For example, for purposes of the study the plants were broken down into departments, and employees were classified in the department in which they had worked the longest. Some employees had changed jobs as many as 30 times. Therefore, employees were classified as belonging to a certain department, such as pliofilm, when in fact they may have spent 10% or less of their total work experience in that department (Exh. 187 B-13 at 25). In like fashion, an employee who worked in the pliofilm operation but spent a greater fraction of his total work experience elsewhere would not be classified under pliofilm operations. Moreover, the researchers noted that benzene was

The Secretary found each of the negative studies cited by respondents (API Br. 15) to be unreliable. The Stallones study of Shell Oil Company workers, for example, "could not determine how many [of the study group] were exposed to benzene" (Pet. App. 111a, 182a-183a). Likewise, the Tabershaw-Cooper study, among other failings, did "not delineate what proportion of the study population had ever been exposed to benzene" (*id.* at 108a); there was no "basis for identifying which workers may have been exposed to benzene" (*ibid.*); and fewer than 10% of the studied employees may have been exposed to benzene (Tr. 1358, 1363, 1411, 1438, 1977). The Thorpe study suffered from at least five substantial methodological faults (Pet. App. 110a, 182a-183a). Respondents are simply wrong in their assertion that the "uncontradicted evidence" proves the risk of cancer at low levels of exposure is "minuscule." The evidence considered as a whole supports both the Secretary's determination that no safe level of exposure to benzene is known and the Secretary's qualitative judgment that long-term exposure to benzene at 10 ppm poses an appreciable health risk.[8]

"suspect as a leukemogenic agent" and that exposure to benzene "should be maintained as far below the Threshold Limit Value as is possible" (*id.* at B. 5).

[8] The inability to quantify the excess risk hardly means that the risk is *de minimis*. For example, the studies (API Br. 4c & n.7) showing that asbestos is a "potent" carcinogen became available only after the Secretary had issued the standard for it. See 37 Fed. Reg. 11318 (1972) (asbestos dust).

c. Respondents' narrower theory also rests on the assertion that the Secretary did not "consider" evidence of costs and benefits and that the court below did no more than hold that the Secretary "must consider evidence on both benefits and costs" (API Br. 27 n.45). Once again, the record belies this assertion. As we explained in our opening brief, the Secretary did consider such evidence in detail. The Secretary simply concluded that the evidence was not sufficiently reliable to establish a safe level of exposure.

In connection with their narrower theory, respondents suggest (API Br. 27 n.45, 70) that it is unnecessary to consider in this case the substantive content of the second step in the court of appeals' test—the "reasonable relationship" requirement—inasmuch as the Secretary was unable to demonstrate quantifiable benefits. We disagree. The Fifth Circuit was moved to require a showing of quantifiable, if approximate, benefits in order to provide the type of "hard evidence" it felt was necessary to satisfy the cost-benefit test of *Aqua Slide 'N' Dive* v. *CPSC*, 569 F.2d 831, 837-844 (5th Cir. 1978). If no such test is required by the Occupational Safety and Health Act, then there is no justification for prohibiting the Secretary from relying on qualitative evidence of risk, especially where reliable quantification of the risk is not possible. We now turn to the arguments made by respondents in support of the actual holding below.

2. In support of the actual holding below, respondents argue that (i) the ultimate goal of the Act is to obtain the maximum possible health and safety benefits from the "finite industrial resources" available for health and safety protection, (ii) any "absolutist interpretation" of the Act will require standards so stringent that they will squander resources that might save more lives if used to combat future hazards, (iii) any such interpretation is thus inconsistent with the goal of the Act and is precluded by "pragmatic" concepts embedded in the statutory language and history, and (iv) the Secretary therefore "must set standards that are reasonable and practical, and in order to do so, must identify, at least roughly, the benefits that each standard is expected to achieve and to consider those benefits in light of the costs imposed by the standard" (API Br. 69-70). To satisfy this requirement the Secretary "must make" a "rough but educated" estimate of the excess risk using risk-assessment techniques (*id.* at 70). "Only if this is done," respondents conclude, can the Secretary carry his "affirmative burden" of "demonstrating" the "reasonableness" of the adopted standard (*ibid.*). If such quantification is not possible for a given substance, then the Secretary may not regulate at all, even when he makes a *qualitative* judgment, based on experience and scientific opinion, that substances pose occupational health hazards.[9]

[9] Respondents attempt to avoid stating directly that the Secretary may not substitute his qualitative judgment where

a. Respondents' contention that the Secretary's regulatory approach will severely misallocate the finite industrial resources available for occupational health protection is incorrect and rests on an extreme and unlikely hypothetical in which the Secretary would require an industry to exhaust its resources available for occupational health protection merely to eliminate a cancer risk known to be minimal. The Act provides ample protection against such extreme regulation and permits "pragmatic" consideration of costs, benefits, and risks in a number of ways.

First, 29 U.S.C. 655(g) requires the Secretary to establish priorities in setting occupational health and safety standards so that the more serious hazards are addressed first. In setting such priorities the Secretary must, of course, consider the relative costs, benefits and risks. Second, 29 U.S.C. 655(b)(5) comes into play after the Secretary decides to issue a new standard. Thus, if a rulemaking record affirmatively demonstrates that an existing standard is highly protective and that imposing a more stringent standard would threaten the industry's ability to respond to other health hazards without significantly improving health protection, the Secretary has dis-

quantitative evidence is too speculative by contending that reliable risk assessments may be performed for long-term, low-level exposure to benzene based on existing data. As explained above (see pages 2-11, *supra*), the Secretary found to the contrary. The Fifth Circuit, moreover, held that such quantitative assessments are a *sine qua non* of regulation under the Act (Pet. App. 18a-19a).

cretion not to issue the standard or to delay regulation until more immediate hazards are addressed. Third, even where the Secretary decides to issue a standard, he considers reliable epidemiological data to determine whether or not a safe level of exposure can be identified. Where such a safe level is determined, the Secretary sets the standard at *that* level, not at the lowest feasible level. Fourth, even where the Secretary requires the lowest feasible level to be achieved, the lowest level will often be dictated by technological feasibility well before the cost of the standard threatens the ability of the affected industry to respond to future hazards. In fact, no standard yet issued has disabled any industry from responding to future hazards.[10] In light of these procedures, the Secretary's view of the Act is hardly an "absolutist interpretation" and does not go nearly so far as the Endangered Species Act or other "absolute" statutes cited by respondents (API Br. 38, 66-68).[11]

[10] In addition, the Secretary may grant a variance from any standard to any employer whose methods of controls will provide at least as much safety and health as would the controls specified in the standard (see 29 U.S.C. 655(d)). The Secretary also takes economic feasibility into account in working out compliance programs for cited employers (see note 44 of our opening brief).

[11] Respondents' dichotomy between "absolute" statutes and "balancing" statutes is fallacious. OSHA is neither absolute nor a balancing statute like the Consumer Product Safety Act, but strikes its own balance in favor of maximum feasible health protection. This obvious difference makes it unnecessary to reply to respondents' treatment of other statutes, except as follows:

(i) The "safety" requirement of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq.*, necessarily requires a balancing of the drug's health benefit against its health risk inasmuch as *all* drugs pose risks to patients. Monetary cost, however, is not a factor. Although *Hess & Clark, Division of Rhodia, Inc.* v. *FDA*, 496 F.2d 975, 993-994 (D.C. Cir. 1974), stated in dictum that the determination of whether an animal drug is safe involves weighing of costs and benefits, the Commissioner of Food and Drugs has specifically refused to follow the dictum. See Diethylstilbestrol; Withdrawal of Approval of New Animal Drug Application; Commissioner's Decision, 44 Fed. Reg. 54852, 54881-54883 (Sept. 21, 1979). Although the prohibition against substances "injurious to living man" in the pre-1972 language of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. (1970 ed.) 135(z)(2)(g) and (h), was construed to require balancing of the health benefits of continued use against health risks, such balancing was clearly suggested by the legislative history. *Environmental Defense Fund, Inc.* v. *Ruckelshaus*, 439 F. 2d 584, 594 n.36 (D.C. Cir. 1971); S. Rep. No. 1379, 89th Cong., 2d Sess. 13, 27, 52, 64-65 (1966).

(ii) Respondents argue (API Br. 67) that the provisions in the Federal Water Pollution Control Act Amendments of 1972, 33 U.S.C. 1311(b)(2)(A), directing that EPA's 1983 effluent limitation guideline reflect "the best available technology economically achievable * * * which will result in reasonable further progress toward * * * eliminating [pollution]," require a comparison of benefits to costs in the setting of limitations. In explaining the conference report on the FWPCA, however, Senator Muskie, "perhaps the Act's primary author" (*E.I. duPont de Nemours & Co.* v. *Train*, 430 U.S. 112, 129 (1977)), stated that in setting limitations for the "best available technology," EPA could consider cost but that "no balancing test will be required." 118 Cong. Rec. 33696 (1972). Even with respect to the 1977 limitations, which required only that limitations be achievable with the "best practicable technology," the statute provides for a limited balancing of costs and benefits: "The balancing test between total cost and effluent reduction benefits is intended to limit the application of technology only where the additional de-

Notwithstanding these features of the Act, respondents urge that once the Secretary decides to regulate a toxic substance whose elimination is technologically feasible (but only at great cost) his approach requires its complete elimination—even if that means fully depleting the affected industry's occupational health resources. Respondents would applaud this allocation were it the best use of the resources.[12] Respondents fear it will not be, however, because, as they construe the Secretary's position, he is barred altogether from considering the possibility that some or all of the resources might be better used to meet other health hazards.[13]

Respondents have falsely portrayed the Secretary's approach. The concept of the lowest feasible level has been developed in a far more realistic manner than respondents' extreme hypothetical would suggest. The costs of toxic substances standards have all been, as in this case, "well within the financial capability" of the affected industries (Pet. App. 163a). No standard has depleted any industry's occupational health resources. Moreover, just as here respondents have not identified any occupational health hazard within their industries more serious than benzene, it is unlikely that such evidence could ever be shown, for the Secretary has sought to address hazards in

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gree of effluent reduction is *wholly out of proportion* to the costs of achieving such marginal level of reduction * * *." *Ibid.* (emphasis added).

(iii) Respondents argue (API Br. 43-45 n.62) that the Federal Mine Safety and Health Act of 1977, 30 U.S.C. (Supp. I) 801 *et seq.*, is far more stringent than OSHA, but that even the Mine Safety Act "does not relieve the Secretary of his obligation to consider risk, benefit and cost evidence." A fortiori, they conclude that here the Secretary is not relieved of that obligation. But the Secretary did consider evidence of risk, benefit, and cost at length. Moreover, respondents neglect to mention that the legislative history of the Mine Act specifically approved and incorporated three leading OSHA cases holding that the Secretary must act under Section 655(b)(5) to protect employees even where "the ultimate facts ~~here~~ in dispute are 'on the frontiers of scientific knowledge,'" and that "standards may be economically feasible even though from the standpoint of employers, they are 'financially burdensome and affect profit margins adversely.'" 123 Cong. Rec. S10221 (daily ed. June 20, 1977); S. Rep. No. 95-181, 95th Cong., 1st Sess. 21-22 (1977), citing *Society of Plastics Industry, Inc.* v. *OSHA*, 509 F. 2d 1301 (2d Cir.), cert. denied, 421 U.S. 992 (1975); *AFL-CIO* v. *Brennan*, 530 F.2d 109 (3d Cir. 1975); *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467, 474 (D.C. Cir. 1974).

[12] Although respondents urge that all risks, benefits, and costs be "considered" in setting standards, they insist (API Br. 7 n.10) that the risk of nonmalignant blood diseases, some fatal, and chromosomal damage due to benzene exposure must be ignored in this case. Contrary to respondents' claim, the Secretary *did* rely on these nonmalignant health risks in deciding to issue the standard (Pet. App. 60a, 78a-98a, 132a, 180a-181a, 212a).

[13] Compliance with the benzene standard may itself substantially reduce the costs of compliance with future standards. Engineering controls like those required by the benzene standard have often proved successful in removing numerous airborne contaminants at the same time. For example, the engineering controls required by the coke oven emissions standard appear to ensure compliance by coke oven batteries with the benzene standard (Pet. App. 145a-146a, 175a, 177a, 191a). Similarly, compliance with the lead standard by primary lead smelters could significantly achieve compliance with the arsenic standard. See 43 Fed. Reg. 54354, 54494 (1978) (lead standard).

order of their severity (see 29 U.S.C. 655(g)). Hence, the Secretary's policy of setting the lowest feasible level is sound and advances the statutory objective.

Respondents would go further and require the assessment of relative cost and risk data for all present and future hazards throughout the industry, if not more broadly, in the establishing of permissible exposure limits for particular substances. But comprehensive risk assessments are not available for many hazards, much less for all hazards within an industry. Prediction of the relationship between an industry's future economic capability and the cost of future OSHA regulations to determine the proper allocation of present resources for the regulation of, say, benzene would be similarly fraught with uncertainty. See *BASF Wyandotte Corp.* v. *Costle*, 598 F.2d 637, 663 n.53 (1st Cir. 1979). In such circumstances, the government must act in the face of uncertainty and must weigh the danger that the health threat is even greater than perceived against the possibility that it is overstated. The advantage of waiting for more complete data must also be weighed against the immediate threat to health. The appropriate resolution of these competing factors is a policy judgment. In resolving such policy questions, the principle of risk aversion in the face of uncertainty—the natural inclination to play it safe, even at the risk of some economic inefficiency—is a well-established concept of public policy (see Pet. App. 97a).

Furthermore, the Secretary has never asserted that he is precluded from considering (where there

is some reason to believe it is so) whether the cost of a standard is sufficiently large that the affected industry will be unable to respond effectively to future health hazards. If that situation were to arise, the statutory phrase "most adequately assures, to the extent feasible" (Section 655(b)(5)) is sufficiently flexible to allow the Secretary to take into account in setting a standard the need for the industry to meet future threats to employee health. In short, there is no realistic basis for respondents' hyperbole that the Secretary's regulatory approach will lead to a severe misallocation of finite occupational health resources.[14]

b. In reply to respondents' contention that "pragmatic" features of the statutory language and history require the Secretary to identify quantifiable benefits and to demonstrate that they bear a reasonable relationship to the costs of the standard, we observe initially that respondents have all but abandoned (API Br. 67 n.96) reliance on the phrase "reasonably necessary or appropriate," the linchpin of the decision below. Our opening brief (at pages 42-47) stated the governing principle that where "the empowering provision of a statute states simply that the agency may 'make * * * such rules and regulations as may be necessary to carry out the provisions of [an] Act,' * * * the validity of a regulation promulgated thereunder will be sustained so long as

[14] "[T]o put an extreme case is not a good test of the fair and just interpretation of any statute." *United States* v. *Dickson*, 40 U.S. (15 Pet.) 141, 164 (1841) (Story, J.).

it is 'reasonably related to the purposes of the enabling legislation.'" *Mourning* v. *Family Publications Service, Inc.*, 411 U.S. 356, 369 (1973) (footnote omitted). Respondents' sole rejoinder (API Br. 67 n.96) is that none of the cases we cited involved statutes that contained the phrase "reasonably necessary or appropriate" and that that phrase, as used in the Consumer Product Safety Act, 15 U.S.C. 2051 *et seq.*, has been construed in two lower court decisions as the Fifth Circuit construed it below.[15]

[15] Congress has used the phrase "reasonably necessary or appropriate" in enabling clauses in several statutes. See, *e.g.*, Section 213 of the Public Utility Act of 1935, 16 U.S.C. 824c; Section 1 of the Veterans Mortgage Insurance Act, 38 U.S.C. 806(g)(4); Section 11(b) of the National School Lunch Act, 42 U.S.C. 1760(b); Section 1406(12) of the Housing and Urban Development Act of 1968, 15 U.S.C. 1705(12). In none of these does the legislative history or the context of the statutory language suggest that Congress meant to limit the agency's rulemaking power by the addition of the word "reasonable." See S. Rep. No. 621, 74th Cong., 1st Sess. 50 (1935) (Public Utility Act); S. Rep. No. 92-311, 92d Cong., 1st Sess. (1971) (Veterans Mortgage Insurance); S. Rep. No. 1123, 90th Cong., 2d Sess. 109 (1968) (Housing Act); H.R. Rep. No. 1585, 90th Cong., 2d Sess. (1962); 114 Cong. Rec. 23681 (1968) (same). To the contrary, in describing the enabling provision in the National School Lunch Act containing the phrase "reasonably necessary or appropriate" (H.R. Rep. No. 684, 79th Cong., 1st Sess. 6 (1945)), the House Report stated that it directed the Secretary of Agriculture to impose certain requirements "as in his opinion are necessary to effectuate the purposes of this title," thus describing the phrase "reasonably necessary or appropriate" in precisely the same way that the Court has traditionally construed enabling clauses (see our opening brief at 42-48.)

Although the Court has never construed the precise phrase "reasonably necessary or appropriate," that phrase could hardly be more rigorous than simply the word "necessary." Indeed, the word "reasonable" in a statutory provision authorizing promulgation of "reasonable regulations" implies no balancing test but merely requires that the regulations be "rational" in light of the purpose of the statute. *United States* v. *Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 752-753 (1972). And, although other provisions in the Consumer Product Safety Act expressly require certain balancing of costs and benefits of safety rules, the phrase "reasonably necessary and appropriate" does not. Hence, to the extent that the decisions relied on that phrase for their results, they were in error. See *Aqua Slide 'N' Dive Corp.* v. *CPSC*, 569 F.2d 831, 844 (5th Cir. 1978); *D. D. Bean & Sons* v. *CPSC*, 574 F.2d 643 (1st Cir. 1978).[16]

c. Respondents' contention (API Br. 41-47, 8b-9b) that the word "feasible" was inserted into 29 U.S.C. 655(b)(5) for the specific purpose of requiring that standards be "reasonable" and "practical," even if true, does not support the holding below. There is nothing unreasonable about a legislative determination that requires standards to be set as low as technologically and economically feasible in order to

[16] Significantly, the phrase was part of the OSHA bill from its inception. At no time in the vigorous debates over the cost of complying with the Secretary's health standards was there ever a suggestion that the phrase was a brake on the Secretary's rulemaking power (see our opening brief at 43 n.36). Respondents do not reply to this argument.

assure that the calculus is weighted in favor of occupational health. Cf. *Usery* v. *Turner Elkhorn Mining Co.*, 428 U.S. 1, 28-29 (1976). A standard, moreover, may be "reasonable" and "practical" even if its benefits are not measurable. Indeed, it is unreasonable and impractical to deny health protection urged by the public health community merely because the number of lives at stake is not susceptible to reliable measurement. Respondents' strained effort to import the words "reasonable" and "practical" into the word "feasible" is therefore beside the point.[17]

[17] In any event, respondents' effort is unpersuasive. In essence, they argue (API Br. 8b-10b) that Senator Javits, the author of the feasibility amendment, intended the word "feasible" to comprehend "reasonable" and "practical." The thread of the argument begins with the Nixon Administration's original bill (S. 2788, 91st Cong., 1st Sess. (1969)), introduced by Senator Javits, which would have required the board responsible for issuing health and safety standards to submit its proposals to certain organizations for a report on "the technical feasibility, reasonableness and practicality of such standard." *Subcomm. on Labor of the Senate Comm. on Labor and Public Welfare*, 92d Cong., 1st Sess. *Legislative History of the Occupational Safety and Health Act of 1970* (Comm. Print 1971) (hereinafter "Leg. Hist.") 38-39. 115 Cong. Rec. 22511 (1969). Respondents claim (API Br. 42) that Senator Javits "described" the provision in the bill calling for a report on "technical feasibility, reasonableness, and practicality" as a "report on the feasibility of the proposed standards," thus collapsing all three words into "feasible."

In fact, however, Senator Javits did not "describe" the report in such terms at all. The "description" of the report was made in President Nixon's message concerning the Administration bill, not by Senator Javits. 115 Cong. Rec. 22511, 22517 (1969). Senator Javits merely asked that the President's lengthy message be printed in the Congressional Record (115 Cong. Rec. 22511 (1969)). Rather than endorsing the message, Senator Javits disassociated himself from the

Administration's bill on a variety of issues, saying that "it may be desirable to go somewhat further than this bill does in strengthening the hand of the Federal Goverment in this area" (*id.* at 22512). Significantly, when Senator Javits actually described his feasibility amendment he consistently used only the word "feasible" and never equated it with "reasonable" or "practical" (Leg. Hist. 197, 418). Furthermore, the President's summary itself did not equate the words "reasonable" or "practical" with "feasible" or even use the words "reasonable" or "practical." The summary stated only that the organizations' reports would address "feasibility" without stating whether it would address other matters. 115 Cong. Rec. 22517 (1969).

The related contention (API Br. 8b) that Senator Javits' feasibility amendment "succeeded in reconciling the Williams bill with the Administration view on this issue [of collapsing the three words into feasible]" ignores the fact that Senator Javits stated that the Senate Committee bill was "an improvement over * * * the administration bill, which contains no criteria for standards at all." (Neither the original Administration bill nor the Steiger-Sikes bill contained any criteria for standards. The Steiger-Sikes bill, moreover, contained no requirement for a report on feasibility, reasonableness or practicality. See Leg. Hist. 36-42, 770-776.) Hence, rather than believing he had incorporated "reasonableness" and "practicality" criteria for standards from the Administration bill or the Steiger-Sikes bill, Senator Javits believed these latter bills had no criteria at all for standards.

Respondents do not seriously dispute that every court of appeals (other than the Fifth Circuit in this case) that has considered the role of costs in promulgating toxic-substance standards has upheld the Secretary's interpretation of the feasibility requirement. Respondents resort to cases construing the word feasible in the OSHA noise standard. *Turner Co., Div. of Olin Corp.* v. *Secretary of Labor and OSHRC*, 561 F.2d 82 (7th Cir. 1977); *RMI Co.* v. *Secretary of Labor and OSHRC*, 594 F.2d 566 (6th Cir. 1979). The noise standard, 29 C.F.R. 1910.95(b)(1), requires employers to utilize "feasible administrative or engineering controls" to reduce employee exposure to excessive noise. It also requires the use of personal protective equipment if administrative or engineering controls are either infeasible or do not reduce

d. Contrary to respondents' argument (API Br. 44-47), the substitution of the word "material" for "any" in 29 U.S.C. 655(b)(5) was not meant to prohibit standards except where there is a measurable, material probability of injury posed by the hazard. To the contrary, "material" modifies "impairment," not the probability that it will occur:

> The Secretary * * * shall set the standard which most adequately assures, to the extent feasible, * * * that no employee will *suffer material impairment of health or functional capacity* * * *

An "impairment of health or functional capacity" is not a "risk." It is a condition or disease, such as illness due to leukemia. An employee, moreover, does not "suffer" a risk. He "suffers" a disease or in-

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exposure to within prescribed limits. *Turner* (which was relied on in *RMI*) reasoned that the noise standard was initially promulgated pursuant to the Walsh-Healey Act, which contained no requirement that standards be feasible, and was adopted as a national consensus standard pursuant to Section 655(a) of OSHA without further consideration of feasibility. 561 F.2d at 85. It reasoned that fairness therefore required that economic feasibility be relevant to enforcing the standard. *Ibid.* We disagree. At most, this calls for interpreting "feasibility" to include consideration of cost—not to require a balancing of costs and benefits. Moreover, the court premised its balancing requirement on the fact that excessive noise is only one of many hazards, many of which are life threatening, which the Act seeks to eliminate; consequently, an employer ought not be required to allocate too much of his finite resources on this lesser hazard. *Id.* at 86; see *Continental Can Co.*, [1976-77] O.S.H.D. (CCH) ¶ 21,009 at 25,256 (1976). As we have discussed, however, the assignment of priorities to hazards is a legislative judgment assigned by the Act to the Secretary.

jury, *i.e.*, an impairment. There is thus no warrant for reading this sentence as if it read: "* * * no employee will suffer [*i.e.*, experience] material *risk of* impairment of health or functional capacity * * *." To do so, moreover, would reduce the command of Section 655(b)(5) to a nullity, for the probability of contracting cancer from exposure to industrial carcinogens, although in excess of normal risks, is small by comparison to other possible causes of death and thus not itself "material." [18]

The Secretary's interpretation of "material" is supported by the judicial construction of the comparable language in 29 U.S.C. 666(j), which sets forth the criteria for determining whether a violation of the Act will be deemed "serious" in the enforcement context. A violation will be deemed serious if, *inter alia*, "there is a substantial probability that death or serious physical harm could result" from the cited hazard. The courts have consistently held that a violation is deemed serious under the Act "where, although the accident itself is merely possible (*i.e.*, in statutory terms, 'could result from a condition'), there is a substantial probability of serious injury *if it does occur*." *Shaw Const., Inc.* v.

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[18] What little legislative history exists on the insertion of the word "material" supports our view that it was addressed to the type of injury, not the probability of injury. Senator Saxbe, one of Senator Dominick's allies in this matter, complained that the phrase "any impairment" would cover mosquito and black-fly bites (Leg. Hist. 345). Senator Williams, a primary sponsor of the legislation, fully supported the amendment and felt that the change "strengthens the objec-

OSHRC, 534 F.2d 1183, 1185, n.4 (5th Cir. 1976) (emphasis added). See *Usery* v. *Hermitage Concrete Pipe Co.*, 584 F.2d 127 (6th Cir. 1978).

e. Contrary to respondents' argument (API Br. 51-55), the second and third sentences of 29 U.S.C. 655(b)(5), and the best-available-evidence clause of the first sentence of Section 655(b)(5) do not support the holding below. Those provisions impose *procedural* requirements to ensure that certain factors are considered. Their substantive weight in setting OSHA standards is dictated by the first sentence of Section 655(b)(5).[19]

Moreover, these procedural imperatives do not prohibit the Secretary from issuing a standard where the number of lives at issue cannot be reliably predicted. The Court has long held that where the

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tives of standards that will protect against physical impairment and loss of function" (Leg. Hist. 503). It is inconceivable that a radical change prohibiting regulation of carcinogens except where a measurably material probability of death would be averted was intended by this virtually unnoted shift in language. See *Edmonds* v. *Compagnie Generale Transantlantique*, No. 78-479 (June 27, 1979), slip op. 9-10.

[19] A statutory requirement that certain factors be "considered" in rulemaking does not require the agencies to give the factors any particular substantive weight or permit a reviewing court to substitute its judgment concerning the weight to be given mandatory considerations. See, *e.g.*, *Kleppe* v. *Sierra Club*, 427 U.S. 390, 410 n.21 (1976); *Aberdeen & Rockfish R.R.* v. *SCRAP*, 422 U.S. 289, 319 (1975); *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 558 (1978); *New York* v. *United States*, 331 U.S. 284, 347-349 (1947).

"benefits" of regulation "do not lend themselves to detailed forecast," agencies have traditionally been "entitled to rely" on their "judgment, based on experience" and "deductions based on the expert knowledge of the agency." *FCC* v. *National Citizens Committee for Broadcasting*, 436 U.S. 775, 797, 814 (1978). "[S]pecific findings of tangible benefit" are not required. *FCC* v. *RCA Communications, Inc.*, 346 U.S. 86, 96 (1953). The agency may rely on its "informed discretion." *Panama Canal Co.* v. *Grace Line, Inc.*, 356 U.S. 309, 317 (1958). Accord, *Permian Basin Area Rate Cases*, 390 U.S. 747, 811 (1968); *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 26-27 (D.C. Cir.), cert. denied, 426 U.S. 941 (1976). These principles apply all the more where "the questions involved in the promulgation of [OSHA] standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination" and rulemaking "must * * * depend to a greater extent upon policy judgments and less upon purely factual analysis." *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467, 474-475 (D.C. Cir. 1974).[20]

Nothing in the provisions cited by respondents alters this established rule. The first and second sentences of Section 655(b)(5) require only that the standard be based on the "best available evidence"

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[20] This passage from *Industrial Union Department* was cited with approval by the Court in *FCC* v. *National Citizens Committee*, *supra*, 436 U.S. at 814.

and on "research, demonstrations, experiments, and such other information as may be appropriate." The benzene standard *is* based on extensive research, demonstrations and experiments, as the voluminous record on file makes clear. The best available evidence was considered and the standard was based on it. The Senate Report, moreover, emphasizes that the Secretary retains discretion in deciding how much and what type of evidence is "appropriate." Leg. Hist. 147. Here, the Secretary concluded that it was not "appropriate" to postpone the standard until, if ever, better dose-response data permits a prediction of "measurable benefits." The third sentence of Section 655(b)(5) merely requires the Secretary to "consider" the "latest available scientific data in the field," the "feasibility" of the standard, "experience gained under this and other health and safety laws" and "attainment of the highest degree of health and safety protection for the employee." Again, however, the Secretary "considered" all these items in great detail. In the absence of a clear statutory directive that incremental risk assessments (and cost-benefit studies) *must* be made in every case, no matter how speculative they may be, these provisions should not be construed to rob the Secretary of his discretion to rely on his qualitative judgment, based on experience and informed by the best available evidence, rather than on extrapolations that the Secretary finds are too speculative to be of meaningful assistance in setting OSHA standards.

Nor does the substantial-evidence test preclude reliance on views, arguments or sound reasoning in evaluating rulemaking evidence. Congress required judicial review on the basis of substantial evidence because of concern that the Secretary of Labor might issue standards without a hearing, an official record, or the opportunity for judicial review. See Leg. Hist. 298-299, 1053. To check this possibility, Congress required factual determinations to be based on substantial evidence in the record, and authorized pre-enforcement review. At no time, however, did the sponsors of the substantial-evidence test state that the Secretary could not employ sound reasoning and judgment to assess the *significance* of the evidence in the record and to decide what, if any, standard might serve the purposes of the Act.[21] This is pre-

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[21] Indeed, the very materials relied on by respondents acknowledge the contrary. Even the six minority members of the House Committee so often cited by respondents felt that the standards should be based on "sound reasons." Leg. Hist. 884. Both the original Nixon Administration bill and the Steiger-Sikes substitute bill would have allowed rulemaking based on "views and arguments" as well as other "evidence" (Leg. Hist. 85, 771-772). Respondents themselves (API Br. 70-74) concede, as the courts of appeals have uniformly held (see our opening brief at 44-45 n.37), that the statutory test only requires the Secretary's factual determinations to be based on substantial evidence and does not subject the policy considerations relied on by the Secretary to any standard of review other than the determination whether they are consistent with the purpose of the Act.

[Footnote continued on page 30]

[21] [Continued]

Respondents' lengthy and distorted rendition of the legislative history on this point deserves a somewhat extended reply:

(i) Respondents claim (API Br. 3b, 6b) that opponents of the Daniels and Williams bills assailed " 'unfair regulatory procedures' which 'permit adoption of administrative regulations based on "views and arguments" rather than solely on probative evidence.' " With one exception, however, the citations to the legislative history have nothing to do with this point and concern exclusively the failure of the bill to use an independent board to set standards (Leg. Hist. 474-475, 877, 982, 1014). The one citation that does bear on this point (*id.* at 884), as mentioned, shows that even the opponents of the statute felt the standard setter should consider "sound reasons."

(ii) Respondents claim (API Br. 53-54 & n.75, 126) that Senator Cook remarked that on judicial review of standards employers would "[n]ever win a case" under the arbitrary-and-capricious test. Actually, Senator Cook's statement had nothing to do with judicial review of health standards. His criticism was confined to a provision in the Senate bill that allowed the Secretary to veto state health and safety plans without adequate judicial review (Leg. Hist. 342-344).

(iii) Respondents compound this error by claiming (API Br. 54, 18b & n.19) that Senator Cook's objection was "one of the chief concerns" that led the full House to reject the Committee bill and to substitute, among other things, the substantial-evidence test. The citations that follow this claim (Leg. Hist. 1013, 1014, 1016, 1053, 1062) do not mention either the arbitrary-and-capricious or the substantial-evidence test. All are concerned with the question whether standards should be set by an independent board (Leg. Hist. 1013, 1014, 1016, 1053, 1062). Only one citation (*id.* at 1053) is relevant to respondents' assertions, but it contradicts their point. Representative Sikes objected to the House Committee bill because it contained "no provision for judicial review of standards." Representative Sikes, however, made quite clear that he would have accepted "the Senate-passed" bill, which *did* "provide such review" (*ibid.*). Since the Senate-passed bill provided for judicial review only under the arbitrary-and-

cisely the function of an expert administrator or agency.

f. Contrary to respondents' suggestion (API Br. 55-64, 11c-14c), the Court should defer to the statutory construction of the Secretary, not the Occupational Health and Safety Commission. The Secretary, not the Commission, is the official entrusted by Congress with the responsibility to study occupational health and safety hazards and to set standards for them. The Commission has no experience or responsibility in investigating or regulating such hazards. The Act does not authorize the Commission to review the validity or wisdom of standards. It may only

capricious standard (see Leg. Hist. 245-246), it is clear that Representative Sikes was objecting solely to the total absence from the House Committee bill of any express provision for pre-enforcement review (*id.* at 940-945).

(iv) Respondents further claim without citation (API Br. 10b) that the second and third sentences of 29 U.S.C. 655(b)(5) were added to prevent the Secretary from acting "on the basis of 'views' or 'arguments.' " However, neither the Senate majority nor minority reports nor any individual Senator ever made such a statement (Leg. Hist. 141-203), and it is totally unsupported. It is true, as respondents relate (API Br. 12b), that the Senate bill was criticized by administration supporters for not requiring a "record" and the substantial-evidence test (Leg. Hist. 298-299). Significantly, however, this was merely a criticism of the informal rulemaking procedure (under 5 U.S.C. 553) allowed by the Senate bill. It was not a criticism of the use of views, arguments or reasoning in the rulemaking process. To the contrary, as mentioned, the Nixon Administration bill and the Steiger-Sikes substitute bill provided for "on the record" rulemaking under the APA, followed by judicial review (Leg. Hist. 110-111).

adjudicate alleged violations of standards drawn by the Secretary. Compare 29 U.S.C. 655(f) with 29 U.S.C. 659. The Commission thus has no occasion to pronounce authoritative constructions of Section 655(b)(5). Its construction of words and phrases in the standards themselves in enforcement cases cannot control the meaning of the rulemaking provisions of the Act. In these circumstances, and in light of the congressional intention not to delegate standard-setting power to an independent commission (see Leg. Hist. 148, 462, 1186-1187, 1191, 1192, 1201-1202), the Secretary's, not the Commission's, view of 29 U.S.C. 655(b)(5) warrants deference.[22]

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[22] Respondents are wrong in their assertion (API Br. 57) that the Secretary and the Assistant Secretary for OSHA have contradicted their position in this case. Although risk assessments were performed in connection with the lead and cotton dust standards, the data were used only to identify health benefits, not to set the level of protection by balancing costs and benefits. See 43 Fed. Reg. 54354, 54427-54431 (1978) (lead); 43 Fed. Reg. 27350, 27378-27379 (1978) (cotton dust); see our opening brief at 68 n.55. The cost-benefit analysis of the cotton dust standard cited by respondents was performed at the expressed request of Congress *after* the standard's promulgation. The report to Congress cautions that "this is a new analysis and does not reflect the decisionmaking process used to promulgate the final standard." U.S. Dept. of Labor, Report to Congress—Cotton Dust: Review of Alternative Technical Standards and Control Technologies 6-7 (May 14, 1979). Similarly, although the preamble to the lead standard stated that the regulation could satisfy the Fifth Circuit's balancing test if one were required, it emphasized that the Secretary "does not accede to the Court's interpretation of the Act." 43 Fed. Reg. 54431 (1978).

The speech by Secretary Marshall simply stated that costs and benefits were "acknowledged"; he did not state that

3. Implicit throughout respondent Rubber Manufacturers Association, Inc.'s submission (RMA Br. 5, 8, 13 n.23) is the suggestion that the dermal prohibi-

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the two factors were balanced in establishing permissible exposure levels for toxic substances. See U.S. Dept. of Labor, Office of Information News Release, Speech Prepared for Delivery by Secretary of Labor Ray Marshall Before the League of Women Voters, Oakland, California at 8 (March 24, 1979). And, after Dr. Bingham's testimony before the Senate Appropriations Committee cited by respondents (API Br. 13c), she sent a letter to the committee chairman to clarify OSHA's position, stating that the agency sets standards by a two-step process, first "determin[ing] * * * the level of protection needed to most adequately assure workers' health," then assessing "the technological and economic capabilities of affected industries" to determine if the standard is "feasible." Appendix B, *infra*, 15a. She explained that the agency "do[es] not believe that a rigid cost-benefit formula should be utilized in the standard setting process. Moreover, incremental cost-benefit analysis is far too theoretical to be applicable, given the limitations of existing methodologies and data bases." *Id.* at 17a.

Nor did the Secretary balance costs and benefits in his 1974 standard regulating 14 carcinogens, as API suggests (API Br. 13c & n.35). Respondents correctly point out that the Secretary set a lower percentage exclusion for "substances [that] are known to be potent human carcinogens." However, the stated intent of all the exclusions was to "avoid substantial obstruction, if not stoppage, of the use of many processes and products which are considered useful in industry and even in cancer research, and about which the record contains very little information" (39 Fed. Reg. 3756, 3759 (1974)), *i.e.* to set a feasible level. Although the Secretary's explanation of his rationale is admittedly ambiguous, that ambiguity was eliminated as the Secretary's regulation of carcinogens evolved, as illustrated by subsequent standards (see pages 67-69 n.55 & 73 n.59 of our opening brief). In any event, the 14-carcinogens standard clearly did not adopt a policy of cost-benefit balancing in the regulation of health hazards.

tion and protective clothing requirements are not feasible. The standard, however, is intended to prohibit dermal and eye contact only with liquids containing more benzene than can feasibly be eliminated. The prohibitions do not apply at all where the liquids contain less than 0.5% benzene (0.1% after three years). Even at the time of the amendment proceeding, at least one supplier sold and several users already used solvents containing less than 0.1% benzene (A. 190, 199, 249). The Secretary found that the three-year phase-in would allow adequate time for suppliers to achieve the 0.1% level (A. 266). In any event, since the feasibility issue was not reached below, it must be assumed in these proceedings that the challenged provisions, together with the percentage exclusion, are entirely feasible.

The issue now presented is whether, having found that the Secretary's conclusion that dermal and eye contact poses a health risk is supported by substantial evidence,[23] the Fifth Circuit correctly held that the Act requires the Secretary to delay the challenged pro-

[23] The substantial evidence supporting this determination is summarized at pages 27-28 of our opening brief. The substantial evidence test, of course, does not require conclusive evidence. *FPC* v. *Florida Power & Light Co.*, 404 U.S. 453, 467-468 (1972). RMA erroneously argues (RMA Br. 14 n.25) that the court below did not hold that substantial evidence supported the finding that dermal and eye contact poses a health risk. To the contrary, the court held that even though substantial evidence supported that finding, the Secretary "in light of OSHA's statutory command" (in the second and third sentences of Section 655(b)(5)), was required to compile a "complete" record by acquiring the Maibach-type study (Pet. App. 25a-27a).

visions until additional and unavailable evidence is acquired. The Secretary can hardly be expected to hire contractors (or request NIOSH) to perform new studies each time it is suggested that such studies might shed new, even significant, light on the best evidence available at the time. Any such requirement would hopelessly bog down the agency in a mire of suggestions for additional research, and no standard would ever issue. Necessarily, the Secretary enjoys discretion to determine when it is "appropriate" to delay promulgation of a standard in order to acquire new evidence. See 29 U.S.C. 655(b)(5) (second sentence) and Leg. Hist. 147, 848. An exercise of such discretion can be reviewed only for the "clearest abuse of discretion" (see our opening brief at 82 n. 67).

Assuming that there ever could be an abuse of discretion in declining to procure additional studies where the Secretary considers the best available evidence and reaches a conclusion based on substantial evidence, there was no abuse of discretion here in the Secretary's decision not to delay the dermal-eye and clothing provisions until a Maibach-type study was performed. As the Secretary explained (Pet. App. 192a-194a, 211a-213a), (i) industry generally did not oppose the provisions now challenged (so long as a feasible percentage exclusion was adopted), (ii) many employers already recognized the health risk and required protective clothing, (iii) NIOSH, ACGIH and other standard-setting organizations recommended elimination of skin contact with liquids containing benzene, (iv) certain studies and experts have concluded that benzene is

"readily adsorbed" into intact skin, although at an unknown rate, (v) "considerable amounts" can be absorbed through damaged skin, and (vi) repeated skin contact with benzene causes skin irritations and dermatitis (see Pet. App. 80a, 212a). In these circumstances, the Secretary did not abuse his discretion in declining to delay the standard (or its challenged provisions)[24] until it could contract with private consultants or induce NIOSH to perform a Maibach-type study, which itself might well have proved inconclusive (as it ultimately did; see pages 79-80 n.63 of our opening brief).[25]

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[24] Contrary to RMA's assertion (RMA Br. 10 n.17, 40-41), the agency's proposed policy for carcinogen regulation, which permits delays in the *initiation* of proceedings to classify a toxic substance as a carcinogen where new scientific evidence will soon be available, does not require the agency to stay a standard *already promulgated*. Nor does it require the agency to develop the new evidence. The policy simply permits postponements in the initiation of a classification proceeding to allow industry and others to submit new evidence in progress. Nonetheless, even after promulgation of a standard, the agency will consider new evidence suggesting need for a modification of the standard (see 29 U.S.C. 655(b)(1)).

[25] Moreover, Dr. Maibach's most recent scientific submission to the Court confirms the Secretary's conclusion that benzene is indeed absorbed through contact with human skin. Significantly, the study also finds that absorption through the palm—the part of the body in direct contact with solvents in tire-building (A. 191)—is substantially greater than in the forearm, at least in the rhesus monkeys used by Dr. Maibach in his test. As a result, RMA (and Drs. Maibach and Johnson) shift ground and argue, utilizing quite a number of questionable assumptions, that the amount of benzene absorbed through a worker's skin is far less than the benzene absorbed through his lungs and therefore that skin absorption need not be protected against. The short answer to this suggestion is that the Secretary must eliminate hazards to the extent feasible. It may not be feasible to achieve airborne concentrations less than one ppm. It is feasible to prohibit dermal and eye absorption.

CONCLUSION

The judgment of the court of appeals should be remanded with instructions to dismiss the petitions for review.

Respectfully submitted.

WADE H. MCCREE, JR.
Solicitor General

OCTOBER 1979

APPENDIX A

RISK ASSESSMENT UNCERTAINTY

The limitations of estimating the number of lives at risk due to long-term, low-level exposure to benzene are illustrated by the Wilson and the EPA studies (A. 15-29, 77-94, 158-179). Although the two calculations were based on the same mathematical method of extrapolation, they employed a number of different assumptions and yielded markedly different results.

The procedure for extrapolating risks was presented in mathematical form in the EPA's report (A. 18-28) and in graphical form in Wilson's report (A. 170). The general principle is that the adverse health effects observed in one or more groups of workers exposed to benzene at various levels can be used to predict the risk to other workers exposed to benzene (now and in the future) at much lower levels. To do so requires explicit assumptions about the relationships between leukemia incidence, intensity of exposure, duration of exposure, and other relevant factors such as age, latent period, etc.

The application of this principle is illustrated by Dr. Wilson's graphical plot of the relationship between the reported incidence of leukemia in workers and the concentrations of benzene to which they were exposed. The result of four epidemiologic studies (by Vigliani, Infante, Thorpe, and Aksoy) were marked on this plot in the form of crosses, the vertical and horizontal lines representing Dr. Wilson's estimates of the uncertainties in each set of data. (Dotted

arrows attached to the Infante and Vigliani data reflect Dr. Wilson's opinion that the exposure levels may have been systematically underestimated in these studies, in addition to the reported range of uncertainty or variation.) Dr. Wilson's estimate of the dose-response relationship for benzene-induced leukemia in man rejects the Infante study and is represented by the *lowest* of the three straight lines drawn on his graph (A. 170-171). This line was then used to estimate the lifetime risk of leukemia in hypothetical workers exposed to benzene at a concentration of 1 ppm (A. 170). Exactly the same procedure was used in the EPA report although it estimated a much higher slope for the dose-response relationship and used it to estimate risks to the general population rather than to workers.

As we show below, each calculation incorporated, explicitly or implicitly, a number of other assumptions, each of which introduces a further wide range of uncertainty into the final estimates of risk. Some of these uncertainties result from lack of scientific understanding of the mechanisms of carcinogenesis, whereas others result from specific deficiencies or gaps in the data on the effects of exposure to benzene. Although EPA pointed out the wide range of uncertainty in their estimates, Dr. Wilson did not do so, leaving an entirely spurious impression of precision.

1. *Selection of data from which to extrapolate* (see Pet. App. 81a, 120a, 122a, 125a). The first step in each calculation was to review the available epidemiologic data and to select one or more sets

of data as a "reference set" from which to extrapolate. Although the various epidemiologic studies on benzene were discussed extensively in the record, neither EPA nor Dr. Wilson reviewed them in detail or gave more than a cursory explanation of their selection. EPA based its estimates upon the results of the Infante study (A. 17-24). On the other hand, Dr. Wilson believed "that the Infante data cannot yet be taken literally" (A. 171) and he drew a much lower line on his graph (A. 170). Dr. Wilson's graph illustrates the great importance of this initial selection of data: the studies of Infante, Vigliani and Aksoy all arrive at different results and a dose-response curve drawn through any one of them would be different from that drawn through the others. In fact, Dr. Wilson's own estimate of the dose-response relationship is incongruent with any of the data. The range of uncertainty due to the initial selections of data is illustrated by comparing the extremes: the Infante study reported a 400% excess risk [1] in workers exposed, according to the Industrial Commission of Ohio, to 10-15 ppm (Pet. App. 105a), whereas the Aksoy study reported a 100% excess risk in workers exposed to about 200 ppm (Pet. App. 101a). Thus, even assuming the reliability of these data and assuming that the studies are comparable in other ways, estimates of the incre-

[1] Dr. Infante reported an incidence five times larger than that in the control populations, which have an incidence of one. The portion of the increased incidence attributable to benzene exposure thus is four times that in the control populations.

mental risk per unit of exposure may vary within a range of 1 to 80 (100/200 to 400/10).

2. *Uncertainties in data on leukemia incidence in the reference populations* (see Pet. App. 81a, 99a, 102a-103a, 107a, 109a, 112a, 122a, 124a). Once a study is selected as the basis for extrapolation, substantial uncertainties may arise from deficiencies in the data on leukemia incidence. These deficiencies, which were extensively discussed in the record, include incomplete follow-up of the exposed workers and both advertent and inadvertent errors in recording causes of death. In addition, there are several different types of leukemia, and benzene may pose different risks for each. For example, in the Infante study the relative risk was five-fold when all types of leukemia were considered, but ten-fold when only myeloid and monocytic leukemia were considered (Pet. App. 107a). Also, in this study only 75% of the exposed cohort were traced, so that the actual incidence of leukemia may have been substantially higher than that recorded (*Id.* at 104a).[2] It is difficult to estimate the possible range of uncertainties resulting from these factors, but it appears likely that the reported frequency of the relevant types of leukemia could easily be underestimated by a factor of two or more.

3. *Uncertainties in the level of exposure of the reference populations* (see Pet. App. 96a, 104a,

[2] Indeed, there was evidence in the record that additional cases of leukemia occurred in the exposed population. See our opening brief at 16 n.17. Dr. Infante assumed that the 25% unaccounted for were still alive, thus underestimating the excess risk (Pet. App. 104a).

105a). Large uncertainties in the range of concentrations of benzene to which the study populations were exposed were discussed in the preamble (Pet. App. 104a). The uncertainties arise not only from the paucity of actual measurements of benzene levels in the various workplaces, but also from the likelihood that the levels would have fluctuated and that the workers' exposure to benzene would have varied due to the use of respirators. Certain evidence showed benzene concentrations in one of the two plants studied by Dr. Infante as having been generally between zero and 10-15 ppm (Pet. App. 105a). EPA, however, estimated that benzene concentrations were generally in the range of 15-100 ppm and calculated that the average exposure might have been in the range 23.7-40 ppm (A. 24-25). Respondents claim that average concentrations were as high as 100 ppm (API Br. 12-13); and Dr. Wilson marked this possibility with a query on his graph (A. 170).[3] Even if the air in work places was this high, personal employee exposure may well have been quite low due to company requirements that employees wear respira-

[3] In this connection, respondents erroneously state (API Br. 13) that, one of "[t]he authors of the Infante Study * * * testified that OSHA had gone 'off the deep end' in interpreting the Study as demonstrating that 'exposure generally below 25 ppm have already induced leukemia." The witness and other authors of the study actually testified that it was impossible to reconstruct accurately the actual exposure levels and that the levels could have been below 10 ppm (Tr. 815, 928, 992, 996, 1141).

tors (see Tr. 807, 966, 972-973, 992, 996). Thus, for the Infante study there is at least a 10-fold range of uncertainty between the highest and lowest estimates of benzene concentrations, without considering any uncertainties resulting from variations within the workplace. (A "conservative" resolution of these uncertainties would require that the steepest possible line be drawn through the Infante "zone" on Wilson's graph. This would result in a slope of about 60 times that used by Dr. Wilson, or a risk of 10^{-4} per year per ppm if all Wilson's other assumptions are followed.)

4. *Uncertainties in the duration of exposure of the reference population* (see Pet. App. 104a; Tr. 767, 934). Carcinogenic risks are dependent on the duration of exposure. OSHA standards must protect workers exposed throughout their working lives. Hence, if observational data are to be used to predict risks to such workers, they should be derived from studies of workers exposed for most or all of their working lives. If they are based on studies of workers exposed for short periods, the calculated risks will be underestimated by unknown factors.

Dr. Wilson made no explicit assumption about the duration of exposure of his reference populations. EPA assumed that all workers in the Infante study were exposed continuously from their entry into the factory until 1975, *i.e.*, for 25-35 years (A. 25). However, there is no support for this assumption in the original report, which merely stated that "all

white males having had direct exposure to benzene *at any time* during the period of January 1, 1940 through December 31, 1949 were selected for study" (Exhibit 2A-271, p. 5, emphasis added). In the absence of information on job turnover among the workers who were studied, there is no reason to assume that the average duration of exposure was 30 years, rather than 15 years, 5 years, or even one year.[4] Thus the lack of information on this factor gives rise to at least a 10-fold range of uncertainty in the calculated risk per unit of exposure.

5. *Uncertainties in the extension of partial-lifetime mortality data to predict full-lifetime risks.* The observational data in the epidemiologic studies usually refer to the mortality experience of workers followed for only *part* of their lifetimes. To estimate the full magnitude of the risks, it is necessary to make assumptions about the excess mortality in the reference groups during the remainder of the workers' lives. Both EPA (A. 24-25) and Dr. Wilson implicitly assumed for the purposes of calculation that the risks observed in the younger years would not increase as the workers aged, so that their lifetime risks of contracting leukemia could be estimated by multiplying the relative risks observed in the studies by the lifetime incidence of leukemia in the

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[4] Dr. Steven H. Lamm modified EPA's calculation by dividing EPA's estimates of risk by 35 to estimate the risk resulting from one year's exposure (his Step 2). For this reason, his estimates of risk are not applicable to the prediction of risks accruing to workers exposed indefinitely at current levels, and they need not be considered further here.

general population.[5] Given the long latency period of cancer, this assumption is not obviously conservative and introduces uncertainities of unknown magnitude. Significantly, over 600 of the 748 employees studied by Dr. Infante were alive in 1975 when he made his calculation.

6. *Uncertainties in the form of the dose-response relationship* (see Pet. App. 97a, 124a, 125a, 160a). Once a point on the dose-response relationship is selected from the wide range of possibilities suggested by the observational data, it is necessary to make assumptions about the mathematical form of the relationship before risks at other exposure levels can be estimated. Both Dr. Wilson and EPA assumed for the purposes of calculation that the dose-response relationship would be linear—*i.e.*, that the excess risks attributable to benzene exposure would be directly proportional to the average concentration of benzene to which the person is exposed during his or her lifetime. Although Dr. Wilson claimed that this assumption is "conservative" (A. 164) and "pessimistic" (A. 171), it is easily possible to envision cases in

[5] For the workers in Dr. Infante's cohort who died of leukemia, the interval between the start of employment and death was 2 to 21 years, with an average of 11.5 years (Exh. 2A-271, Table 3). Since the workers who actually died of leukemia are likely to be those with above-average exposure, it is unlikely that the average duration of exposure in the entire cohort could have been that long. The study does not report the average duration of exposure in the entire cohort.

which such an assumption would substantially underestimate risks at low doses.[6]

7. *Uncertainties due to other unrecorded factors* (see Pet. App. 80a-98a, 103a, 117a-118a). Extrapolation of dose-response data from one exposed group to predict risks in another involves the implicit assumption that the groups are similar to each other in all relevant characteristics except the exposure to benzene. Other factors that are known to influence carcinogenic risks include age, sex, smoking habits, and exposure to other chemicals or to radiation. There is little or no information on these factors that would allow comparison of the reference groups with the current workers whose risks are to be calculated. Moreover, Dr. Wilson (A. 171) assumed "conservatively" that for every leukemia induced by benzene "there is one additional cancer death at an unknown site," and for this reason he multiplied the estimate of leukemia risk by a factor of two to obtain estimates of total cancer risk. The basis for his selection of a factor of two is not stated, and it introduces uncertainties of unknown magnitude. It is known, furthermore, that there are additional ben-

[6] An actual example of such a case is presented by recent experimental data on vinyl chloride, which show a dose-response curve rising steeply at low doses and then becoming progressively less steep as the doses were increased. See Scientific Committee of the Food Safety Council, Proposed System for Food Safety Assessment, 16 *Food and Cosmetics Toxicology* (Supp.) 128 (Dec. 1978). The Scientific Committee fitted these data to a mathematical curve which is much more "conservative" at low doses than the linear model used by Dr. Wilson. *Id.* at 115.

zene-related risks other than cancer, such as aplastic anemia which Wilson ignored.

8. *Uncertainties in the number of exposed workers and in their level of exposure* (See Pet. App. 69a, 138a; A. 90). Dr. Wilson (A. 175) based his calculation of risks to the workers presently exposed on a study which estimated that 30,000 workers have 8-hour working day average concentrations above the proposed 1 ppm standard. Dr. Wilson further assumed that these 30,000 workers are now exposed to an average of 3 ppm (A. 176). Although the Secretary regards the estimate of 30,000 workers as reasonable, its accuracy is unknown (see Exh. 5.A at 3-5; Pet. App. 138a). Moreover, Dr. Wilson's assumption that the average exposure level is 3 ppm appears completely arbitrary. It would be more conservative to assume that the average exposure level of the workers is as high as the 10 ppm permitted under the present standard. Thus, the incompleteness of the information on current exposure to benzene introduces uncertainties into the risk estimates of at least a factor of 3.

9. *The total range of uncertainty* (see Pet. App. 160a). The use of the fragmentary existing data on excess cancer incidence in workers formerly exposed to benzene to estimate lifetime risks to workers currently exposed to different levels thus involves a number of assumptions, explicit and implicit, each of which introduces a substantial range of uncertainty into the calculations. Because risk extrapolation is a sequential procedure in which each step utilizes the

results of the preceding steps, these uncertainties expand as the calculation progresses and combine multiplicatively to yield an extremely wide range of uncertainty in the final estimates.

It is difficult to estimate the full magnitude of this range of uncertainty, because information is lacking about the consequences of many of the assumptions. However, as shown above, there is at least an 80-fold variation between the dose-response data in various epidemiologic studies; in addition, there may be uncertainties ranging up to ten-fold resulting from lack of knowledge of the duration of exposure in these studies and up to three-fold resulting from lack of knowledge of current exposure. Since the uncertainties combine multiplicatively, these factors alone introduce uncertainties into the final estimates of risk that may range from one to 2,400. Additional uncertainties of unknown magnitude are introduced by the other factors discussed above, including incomplete follow-up of the reference populations, errors in recording causes of death, fluctuations in exposure, extrapolation of partial-lifetime to full-time risks, possible risks from other diseases, uncertainties in the form of the dose-response and duration-response relationships, age, sex, and synergisms with other risk factors.

So many factors are involved that the range between the lowest and highest reasonable estimates of risks may range into the tens of thousands, if not millions. This range of uncertainty cannot be ignored. Although EPA recognized that its own esti-

mates of general population risks could for these reasons "easily be in error by several orders of magnitude" (A. 25), Dr. Wilson presented only a single estimate of risks and did not discuss uncertainties except to claim that his estimate was conservative and pessimistic. The analysis above shows, to the contrary, that his estimate of risk could easily be too low by many orders of magnitude.

The following "risk assessment," using assumptions different from those used by Dr. Wilson (yet wholly reasonable) illustrates the multiplicative effect of these uncertainties.

1. Rather than reject Dr. Infante's findings, as Dr. Wilson did, our counterexample accepts Dr. Infante's finding that there were 5.6 excess leukemias among the 748 workers whose vital status was studied through 1975. We also assume that the average level of benzene to which workers were actually exposed was 10 ppm (see pages 5a-6a, *supra*).

2. Next, we adjust the number of excess leukemias found by Dr. Infante to take into account uncertainties in his data: (i) we assume that each employee in his cohort was exposed for five years (see pages 6a-7a, *supra*); (ii) Dr. Infante reported 5.6 excess deaths through 1975 when over 600 of the cohort were still alive (see page 8a, *supra*); due to the long latency period, we assume that benzene-induced leukemias will continue to emerge as the cohort ages; we also assume that Dr. Infante missed some leukemias among the 25% of the cohort whose vital status was unknown in 1975 (see page 4a, *supra*),

so that a total of 17 excess leukemias will result over the entire lifetime of the 748 members of the cohort.[7] These adjustments mean that approximately 23 of every 1000 employees exposed for five years at 10 ppm will be expected to die of leukemia as a result of occupational exposure.

3. If we assume that there are 30,000 job positions in the United States now exposed at 10 ppm and that job turnover is such that these positions are filled anew every five years (as we assume was true in the Infante study) then 690 leukemias would eventually result for every five years of exposure at 10 ppm. If there are 60,000 job positions (see page 10a, *supra*), then there would eventually be 1380 leukemias for every five years of occupational exposure. Dr. Wilson predicted 2 cancers every six years (or roughly 1.7 every five years). Thus, simply

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[7] Assuming that the missing 25% of the cohort experienced the same incidence of leukemia as the 75% accounted for, Dr. Infante would have found 9.3 leukemias out of 748 workers. Since only 1.38 leukemias were expected among 748 persons, given their ages through 1975 when the study ended (see Pet. App. 105a), the relative risk of benzene-induced leukemia would be 6.76 (9.3/1.38). The *lifetime* normal risk of leukemia in the general population is 0.39% (A. 20-21) so that in a cohort of 748 persons, 2.92 "normal" leukemias would be expected in their entire lifetimes. Assuming conservatively that the relative risk of benzene-induced leukemias remains constant at 6.96 as the cohort ages, then 19.7 total leukemias (6.76 x 2.92) and 17 excess leukemias (due solely to benzene exposure) would be expected. (Given the long latency period, a conservative extrapolation might well assume even more than 17 excess deaths will appear as the cohort ages, although, for purposes of illustration, we have not made that assumption).

by making different yet reasonable assumptions, we obtain a result about 800 times greater than did Dr. Wilson—illustrating the wide range of uncertainty presented by attempts to quantify the health risk for benzene. (These numbers, moreover, do not include death due to nonmalignant diseases caused by benzene.)

APPENDIX B

14 MAR 1979

Honorable Warren G. Magnuson
Chairman
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Senator Magnuson:

A review of the transcript of our hearings before your Appropriations Committee reveals a misunderstanding on my part in responding to a series of questions regarding cost-benefit analysis. I would like to clarify for the record the agency's position on this issue.

The Occupational Safety and Health Act is primarily prevention-oriented public health legislation which establishes the right of workers to safe and healthful working conditions. Yet the purpose of the Act is not to protect workers by putting employers out of business. Nor is it to cause employers to spend more money than necessary to protect workers. Therefore, the first step in our standard-setting process is to determine on the basis of scientific evidence the level of protection needed to most adequately assure workers' health and safety. Then an assessment of the technological and economic capabilities of affected industries is made. OSHA does not set permissible exposure limits that are technologically infeasible. In addition, the agency seeks to avoid significant economic disruption among affected industries. Both of these factors have been defined by the courts.

In setting standards, OSHA believes that important information is gained from economic studies which indicate the most cost-effective means of providing adequate protection for workers (i.e., achieving a prescribed level of worker protection in the least costly manner). However, such studies are presently somewhat speculative since no reliable means exist for assessing the costs of compliance. Moreover, determining whether the costs of a regulation equal the benefits at the margin cannot be done given existing methodologies and data. For example, present accounting procedures do not readily permit the identification of expenditures for regulation apart from those for capitalization, operation and maintenance. It is also difficult to anticipate, prior to the promulgation of a regulation, its effects on technological and industrial innovation. In some cases American industry has found new and less costly methods of compliance than were anticipated prior to the issuance of a standard.

Likewise, it is difficult to quantify or to express accurately in monetary terms all the benefits of regulation. Failure to reduce workplace hazards results in enormous costs in terms of workers' compensation, disability, medical expenses and health insurance, lost productivity, and worker turnover, but it is not feasible at this time to make a reasonable association between types of accidents or illnesses and subsequent costs. Moreover, some benefits such as decreased pain and suffering, and a better community and family life, can never be quantified.

OSHA is concerned about the effects of its regulations on the allocation of resources in the private sector. With this in mind, the agency has committed itself to a substantial upgrading of pre-regulation analyses. More effective analytical methods and improved data bases are now being developed. However, OSHA is also concerned that economic considerations not be the primary basis for decision-making. We do not believe that workers should be viewed as "human capital." They are human beings with non-quantifiable value, personal needs and feelings. Their health should not be determined by the outcome of a mathematical equation. OSHA therefore favors the use of a "cost effectiveness" approach to setting standards. That is, the agency examines alternative means for achieving prescribed levels of worker protection.

In summary, OSHA will continue to improve the feasibility analyses which accompany new standards. An examination of recent regulations (e.g., cotton dust and lead) reveals a significant improvement in this area over the last several years. However, we do not believe that a rigid cost-benefit formula should be utilized in the standard-setting process. Moreover, incremental cost-benefit analysis is far too theoretical to be applicable, given the limitations of existing methodologies and data bases. If such data and analytical techniques existed, we are confident the evidence would show that in the long run the costs of OSHA regulations are fully justified in terms of health, equity and economic efficiency.

I hope this statement will clarify OSHA's position on the use of cost-benefit analysis in setting health and safety standards. Given the strong public and Congressional interest in this issue, I believe it would be a useful contribution to insert this letter into the record of OSHA's appropriations hearings of February 22, 1979.

Sincerely,

Eula Bingham
Assistant Secretary
Occupational Safety and Health

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